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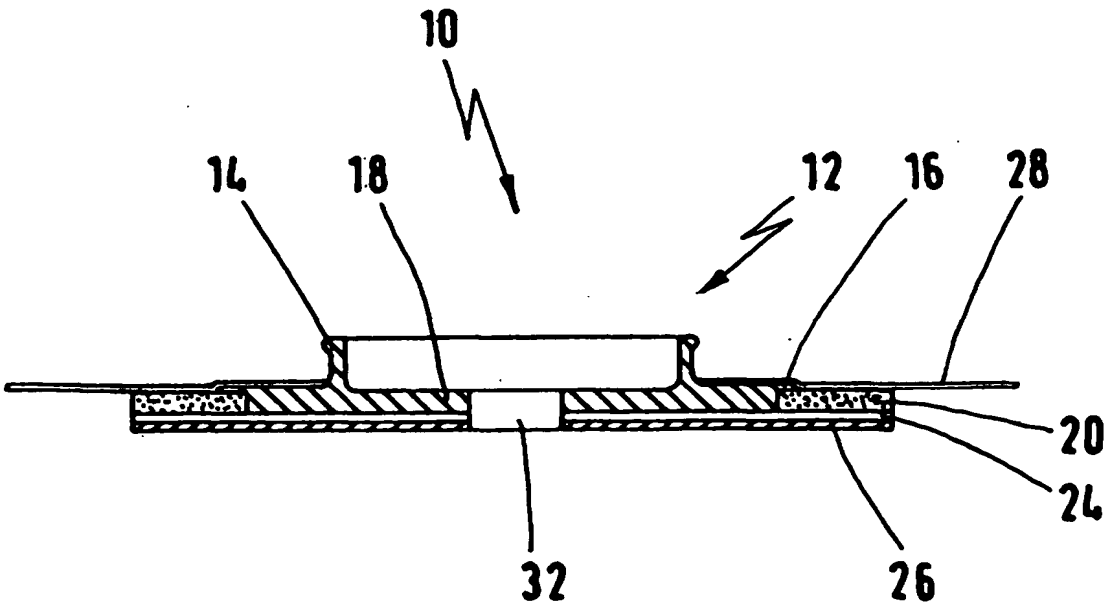
(54) **Title:** AN OSTOMY COUPLING



(57) **Abstract:** The present invention concerns an ostomy coupling (16) for use in mounting an ostomy bag about a stoma. The ostomy coupling comprises a baseplate (12) having a bore (32) and a shoulder (18), a foam rubber annulus (20) circumscribing the shoulder of the baseplate, and an adhesive layer (26) permanently affixed to the shoulder of the baseplate and to the foam rubber annulus.

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AN OSTOMY COUPLING

The present invention concerns an ostomy coupling.

For many ostomates, use of various ostomy appliances, in particular ostomy flanges, results in skin irritation of one form or other. Approximately two thirds of ostomates will experience, at one time or other, a skin problem as a result of using or wearing an ostomy appliance. A large percentage of said skin problems arise due to leakage of waste from the stoma onto the surrounding skin, thereby causing skin irritation. This often occurs due to the rigidity of existing ostomy flanges which, in use, are incapable of sufficiently contouring to the patient's body, therefore allowing the stoma contents to leak beneath the flange and onto the surrounding skin.

Also, due to leakage, conventional flanges have a reduced capacity to adhere to the skin surrounding the site of the stoma, requiring as a result, more frequent changing of the flange. This results in increased irritation and therefore an increased likelihood of infection. Once an infection has set in, it can often result in a self-sustaining situation whereby an ostomy flange cannot be worn due to the infection, which therefore allows further leakage onto the infected skin, preventing any rash or infection present from healing.

One solution currently employed to overcome the problem of adherence of ostomy flanges to the stoma site is in the application of a more aggressive adhesive to the

skin contacting face of the flange to provide sufficient support in order to maintain the flange in contact with the skin for longer. However, this has the negative effect of resulting in further skin irritation when removing the flange, as the aggressive adhesive tends to pull or tear at the skin surrounding the stoma during removal of the flange.

A further common cause of skin irritation in ostomates is an allergic reaction to certain microporous adhesive films which are used as a support overlaid on the ostomy flange and adhered to the patient's skin surrounding the flange. Present ostomy flanges will generally have to be changed approximately four to seven times a week, thereby further increasing the irritation caused by the microporous adhesive film in separating it from the skin.

The present invention seeks to overcome the problems associated with prior art ostomy flanges by providing an ostomy flange which provides support and durability, in use, such as to enable the flange to be worn for extended periods of time.

The present invention further seeks to overcome the problems of the prior art by providing an ostomy flange comprised of materials which reduce infection and promote healing of skin surrounding the flange.

The present invention substantially alleviates these problems by providing an ostomy coupling for receiving an ostomy appliance, the ostomy coupling comprising a baseplate from an upper face of which baseplate, in

use, extends a mount for receiving the ostomy appliance, the baseplate further including a bore and a shoulder; a foam rubber annulus circumscribing the shoulder of the baseplate; and an adhesive layer permanently affixed to the shoulder of the baseplate and to the foam rubber annulus.

Preferably, the ostomy coupling further comprises an adhesive backed polymeric film adhered to the upper face of the baseplate and extending radially outwardly from the baseplate, the polymeric film including an aperture through which the mount projects.

Preferably, the ostomy coupling comprises a polymeric layer disposed between the foam rubber annulus and the adhesive layer.

Preferably, the foam rubber annulus, in use, distorts to absorb loading induced stresses transmitted to the coupling as a result of movement of the ostomy appliance such as to reduce the transfer of said stresses to the adhesive layer.

Preferably, the mount is in the form of an annular rib.

Preferably, the foam rubber annulus is hydrocolloid in nature.

Preferably, the adhesive layer is hydrocolloid in nature.

Preferably, the polymeric layer is hydrocolloid in nature.

Preferably, at least a lower surface of the baseplate (and most preferably both surfaces) is concave in nature such that the coupling curves downwardly towards the bore, in order to facilitate use thereof with a flattened or recessed stoma.

As used herein, the term "coupling" is intended to mean a device capable of adhering to the skin around the site of a stoma and having fixing means in the form of a mount to permit an ostomy appliance, for example, an ostomy bag, to be secured thereto.

As used herein, the term "ostomy appliance" is intended to include an ostomy bag which, in use, is secured to the site of a stoma by means of an ostomy coupling.

As used herein, the term "stoma" is intended to mean a surgically constructed opening, especially an opening in the abdominal wall that permits the passage of waste after a urostomy, colostomy or iliostomy .

As used herein, the term "hydrocolloid" is intended to mean any of several substances that form gels with water (such as, but not limited to, algenic acid salts, agar, carrageenan, and related polysaccharide gums or colloids) and that are used especially in the production of hydrocolloid dressings to promote wound healing.

As used herein, the term "foam rubber" is intended to mean a rubber made from latex or other suitable rubber by foaming (beating air into the rubber), prior to

vulcanisation. Preferably, the foam rubber is a light firm spongy rubber.

As used herein, the term "polymeric" is intended to mean of, relating to, or consisting of a polymer.

As used herein, the term "concave" is intended to mean a surface which is curved or bulged inwardly like the inner surface of a sphere, such as to dip radially inwardly from an outer edge towards the centre. In the present context, the term "concave" is intended to be applied to at least the lower surface of the baseplate.

The present invention will now be described with reference to the accompanying drawings, in which;

Figure 1 illustrates a sectioned side elevation of an ostomy coupling according to the present invention;

Figure 2 illustrates an exploded perspective view of the ostomy coupling of Figure 1; and

Figure 3 illustrates a sectioned side elevation of an alternative embodiment of an ostomy coupling according to the present invention.

Referring now to the Figures 1 and 2 of the drawings, there is illustrated an ostomy coupling, generally indicated as 10, for location around a patient's stoma (not shown), facilitating the use of an ostomy bag or the like. The coupling 10 incorporates a central bore 32 through which, in use, the patient's stoma (not

shown) extends. The coupling 10 is formed from five main components, the backbone of which is a baseplate 12 formed from a resiliently deformable plastics material. The purpose of the baseplate 12 is to act as a support or anchor from which an ostomy bag (not shown) may be suspended. As during the course of use, the ostomy bag fills with waste, there is a considerable load exerted on the coupling 10, which must therefore provide adequate support to permit the comfortable and effective use of same, preferably over a number of days.

The baseplate 12 includes a mount in the form of an annular rib 14 projecting outwardly from a body 16 thereof, and a shoulder 18 projecting inwardly from the body 16 thereof, the annular rib 14 being shaped and dimensioned to engage with a corresponding fixture (not shown) on the ostomy bag (not shown). The shoulder 18 is shaped and dimensioned for a substantially snug fit with an annulus 20 (see below). The body 16 of the baseplate 12 extends radially outwardly from the shoulder 18 and has a diameter less than that of the annulus 20, thereby partially covering the upper face of the annulus 20. Therefore, the fixture (not shown) is pressed, in use, into substantially fluid tight engagement with the annular rib 14, thereby retaining the ostomy bag (not shown) in register with the coupling 10. It will be appreciated that any suitable alternative fixing means (not shown) may be used in place of the annular rib 14 in order to connect an ostomy bag (not shown) to the coupling 10, the ostomy bag therefore being provided with a corresponding fixture (not shown) for connection thereto.

Surrounding the shoulder 18 of the baseplate 12 is the foam rubber annulus 20. The annulus 20 includes a circular void 22 in which the shoulder 18 of the baseplate 12 is located. The circular void 22 has a depth and diameter substantially equal to that of the shoulder 18 in order to ensure a secure fit between the baseplate 12 and the annulus 20. One preferred material for the foam rubber annulus 20 is Granuflex™, as manufactured by ConvaTec Limited of Harrington House, Milton Road, Ickenham, Oxbridge, UB10 8PU, United Kingdom, which consists of a thin polyurethane foam sheet bonded onto a semi-permeable polyurethane film, which is impermeable to exudate and microorganisms including HIV virus. The surface of the Granuflex™ is coated with a crosslink adhesive mask containing a dispersion of gelatine, pectin and carboxymethyl cellulose together with other polymers and adhesives forming a flexible wafer. When the Granuflex™ comes into contact with wound exudate, the polysaccharides and other polymers absorb water and swell, forming a gel. The moist conditions produced thereunder promote fibrinolysis, angiogenisis and wound healing, without causing maceration. The gel which is formed as a result of the absorption of wound exudate is not mobile and free running but held within the structure of the adhesive matrix of the annulus 20.

The annulus 20 and the shoulder 18 are adhered to a polymeric layer 24 having a diameter substantially equal to that of the annulus 20 and having an aperture corresponding to the bore 32. The polymeric layer 24

is in turn adhered to an adhesive layer 26 which, in use, contacts the patient's skin around the stoma. The adhesive layer 26 is preferably a hydrocolloid in the form of an adhesive wafer dressing which contains gel forming agents, such as sodium carboxymethylcellulose (NaCMC), gelatin or a mixture thereof. These agents are combined with elastomers and adhesives to form an absorbent, self adhesive, water proof wafer. In the presence of wound exudate, hydrocolloids absorb liquid and form a gel, the properties of which are determined by the nature of the formulation. Some dressings form a cohesive gel, which is largely contained within the adhesive matrix; while others form more mobile, less viscous gels which are not contained within the dressing structure. In the intact state, most hydrocolloids are impermeable to water vapour, but as the gelling process takes place, the dressing becomes progressively more permeable. The loss of water through the dressing in this way enhances the ability of the product to cope with exudate production. Furthermore, hydrocolloids have a property known as wet tack, by which is meant that they can adhere to a moist site as well as a dry one. The polymeric layer 24 is preferably formed from Mactac™ double sided adhesive as manufactured by Mactac Europe S.A. of Boulevard Kennedy, B-7060 Soigines, Belgium. The adhesive layer 26 is preferably formed from Duoderm™, as manufactured by Convatec Limited of Harrington House, Milton Road, Ickenham, Oxbridge, UB10 8PU, United Kingdom, Duoderm™ being a thin wound dressing consisting of a highly flexible film outer cover and an adhesive layer that contains unique adhesive particles that allow the

adhesive to work on both dry and moist skin surfaces, interacting with wound exudate to produce a soft gel mass that enables removal of the dressing with minimal damage to newly formed skin.

It is believed that hydrocolloids will granulate and epithelialize wounds that are draining low to moderate amounts of exudate, while helping to promote autolytic debridement by keeping wound exudate in contact with necrotic tissue. Autolytic debridement is the breakdown of all or part of a cell or tissue by self produced enzymes resulting in the removal of lacerated, devitalised or contaminated cells or tissue.

The adhesive layer 26, in order to maintain the flexibility of the overall coupling 10, is relatively thin. For this reason, the adhesive layer 26 is susceptible to heat degradation which will occur, in use, as a result of the heat from a patient's body. The polymeric layer 24 is therefore provided in face-to-face contact with the adhesive layer 26, and facilitates dissipation of heat from the adhesive layer 26, thereby extending the life thereof. This ensures that the coupling 10 is capable of remaining adhered to a patient's skin for an extended period of time.

In use, the adhesive layer 26 of the coupling 10 is adhered to the abdominal wall around the site of the stoma, the stoma itself projecting through the central bore 32. In this way, the stoma is in fluid communication with the interior of the ostomy bag (not shown) which is secured to the coupling 10. The central bore 32 is sized so as not to be in direct

contact with the stoma, as rubbing of the central bore 32 against the stoma causes discomfort to the wearer, and may lead to an infection. However, over sizing of the central bore 32 therefore allows, in use, quantities of waste which issues from the stoma to migrate between the stoma and the central bore 32. Such waste, being generally acidic in nature, would conventionally tend to corrode the coupling 10 around the central bore 32, exposing the skin beneath the coupling 10 to the waste, again resulting in a rash or infection. The polymeric layer 24 is therefore preferably formed from a material which is resistant to corrosion from the stoma contents. It is also important that the polymeric layer 24 utilises a strong adhesive in order to prevent the various layers of the coupling 10 from parting in use under the weight of an ostomy bag (not shown). The polymeric layer 24 should also be relatively thin in order to maintain the flexibility of the overall coupling 10.

For the reasons mentioned above, at least one, and preferably both of the adhesive layer 26 and the polymeric layer 24 are formed from hydrocolloid materials, which are therefore capable of absorbing waste which comes into contact therewith, such as to prevent contact of said waste with the skin. Furthermore, if said waste is not so absorbed, it will tend to migrate between the adhesive layer 26 and the patient's skin, thereby reducing the adhesion thereof to the skin, which will ultimately reduce the wear time of the coupling 10, as is the case with conventional ostomy couplings (not shown).

It is also found that the foam rubber used for the annulus 20 is prone to wrinkling and deformation in use due to the forces acting thereon, said wrinkling and deformation leading to degradation of the annulus 20 and therefore the coupling 10 itself. It is found that the addition of the polymeric layer 24 substantially reduces this wrinkling and deformation, thereby increasing the durability of the coupling 10. The foam rubber used in the annulus 20 is also preferably hydrocolloid in nature, in order to absorb any excess exudate or waste which may come into contact therewith. The annulus 20 lends a high degree of flexibility to the coupling 10, allowing it to contour to a patient's body. The annulus 20, being a foam rubber, distorts to permit minor relative movement between the baseplate 12 and the adhesive layer 26. It will be appreciated that, when a wearer of the coupling 10 is mobile or active, the ostomy bag (not shown) mounted to the coupling 10 will undergo some movement, being freely dependent from the coupling 10, said movement therefore being transmitted to the coupling 10. Without the flexibility embodied within the coupling 10 by the provision of the foam rubber annulus 20, the movement of the baseplate 12 would soon draw the adhesive layer 26 away from the patient's skin, resulting in failure of the coupling 10. The annulus 20 therefore effectively acts to absorb a substantial amount of the shock transmitted to the coupling 10 from the ostomy bag (not shown), such as to increase the durability of the coupling 10, while maintaining the adhesive layer 26 in contact with the patients skin. This further results in reducing or preventing leakage of the stoma contents onto the patient's skin beneath the adhesive

layer 26. Again this will reduce or prevent associated skin irritation and infection.

The coupling 10 further includes a thin polymeric film 28 which is located on and adhered to the baseplate 12, and extends radially beyond the circumference of each of the annulus 20, the polymeric layer 24 and the adhesive layer 26. The polymeric film 28 includes a central opening 30 which is located, in use, concentrically about the annular rib 14. The polymeric film 28 extends radially outwardly beyond the remaining components of the coupling 10, and is adhered, in use, about the remaining components of the coupling 10 to the patient's skin in order to act as an additional support to the coupling 10. The polymeric film 28 is also substantially waterproof and capable of sealing the coupling 10 to the patient's skin in a watertight manner. This therefore allows a patient to wash with the coupling 10 in place, further facilitating the longevity of the coupling 10. The polymeric film 28 is preferably formed from Tegaderm™ as manufactured by 3M Healthcare Limited of PO Box 1, 3M House, Market Place, Bracknell, Berkshire, RG12 1JU, United Kingdom, Tegaderm™ consisting of a thin polyurethane membrane coated with a layer of an acrylic adhesive. The dressing, which is permeable to both water vapour and oxygen, is impermeable to microorganisms and once in position, it provides an effective barrier to external contamination, whilst producing a moist environment at the surface of the wound by reducing water vapour lost from the exposed tissue. Under these conditions in shallow wounds, scab formation is prevented and

epidermal regeneration takes place at an enhanced rate, compared with that which occurs in wounds treated with traditional dry dressing.

Furthermore, in the unlikely event that the coupling 10 begins to leak beneath the adhesive layer 26, the polymeric film 28, being waterproof, will prevent leakage beyond the circumference of the adhesive layer 26. This therefore results in discoloration of the annulus 20, as it absorbs the leaking waste, alerting the wearer that it is necessary to change the coupling 10. With conventional ostomy flanges (not shown), no such warning is given, and it is often the case that the unexpected leakage results in soiling of the wearer's clothing.

It has been found, in use, that the coupling 10 of the present invention may remain in working order on a patient's skin for approximately 7-10 days, thereby reducing the frequency at which the coupling 10 must be replaced. It will therefore be appreciated that this will reduce considerably the irritation to the skin associated with the regular removal and adherence of ostomy couplings from the patient's skin. Furthermore, each of the constituent components of the coupling 10 undergoes gamma ray sterilisation prior to construction of the coupling 10. It will be understood that, due to the durability of the coupling 10, and therefore the reduced number of couplings 10 used by a patient, a considerable saving in cost may be achieved by use of the present invention.

Referring now to Figure 3 of the drawings, there is illustrated a second embodiment of a coupling according to the invention, generally indicated as 110, for securing an ostomy bag (not shown) about a stoma (not shown). In this second embodiment, like components have been accorded like reference numerals, and unless explicitly stated, perform the same function as hereinbefore described with reference to the coupling 10 of the first embodiment. The coupling 110 comprises a baseplate 112 having a body 116, a shoulder 118 extending therefrom, and an annular rib 114 projecting outwardly from the body 116. The annular rib 114 is adapted to receive, in substantially fluid tight engagement, the ostomy bag (not shown) for collecting waste which issues from the stoma (not shown). The construction of the coupling 110 differs from that of the coupling 10 in that the polymeric layer 24 and the polymeric film 28 of the coupling 10 are omitted, thereby providing the coupling 110 with greater flexibility, but consequently less durability, when compared to the coupling 10. The coupling 110 includes a foam rubber annulus 120, thereby including all of the benefits as hereinbefore described, and affords the wearer a greater degree of comfort with the coupling 110 in place, due to the increased flexibility thereof. However, the coupling 110 has been found to remain in working order on a patient's skin for the reduced term of approximately 3 to 7 days, as opposed to the 7 to 10 days of the coupling 110 of the first embodiment.

It will be appreciated that the couplings 10, 110, may be produced having a concave form, in order to allow the couplings 10, 110, to be used with a stoma (not

shown) which is flattened or recessed within the abdominal wall. Such an alteration of the shape of the couplings 10, 110, in no way affects the performance thereof as hereinbefore described.

CLAIMS

1. An ostomy coupling for receiving an ostomy appliance, the ostomy coupling comprising a baseplate from an upper face of which, in use, extends a mount for receiving the ostomy appliance, the baseplate further including a bore and a shoulder; a foam rubber annulus circumscribing the shoulder of the baseplate; and an adhesive layer permanently affixed to the shoulder of the baseplate and to the foam rubber annulus.

2. An ostomy coupling according to Claim 1, further comprising an adhesive backed polymeric film adhered to the upper face of the baseplate and extending radially outwardly from the baseplate, the polymeric film including an aperture through which the mount projects.

3. An ostomy coupling according to any preceding claim wherein the foam rubber annulus is substantially the same thickness as the shoulder of the baseplate, such as to be substantially co-planar therewith.

4. An ostomy coupling according to any preceding claim wherein the foam rubber annulus, in use, distorts to absorb loading induced stresses transmitted to the coupling as a result of movement of the ostomy appliance such as to reduce the transfer of said stresses to the adhesive layer.

5. An ostomy coupling according to any preceding claim further comprising a polymeric layer disposed between the foam rubber annulus and the adhesive layer.

6. An ostomy coupling according to any preceding claim wherein the mount is in the form of an annular rib.

7. An ostomy coupling according to any preceding claim wherein the foam rubber annulus is hydrocolloid in nature.

8. An ostomy coupling according to any preceding claim wherein the adhesive layer is hydrocolloid in nature.

9. An ostomy coupling according to any of Claims 6 to 8 wherein the polymeric layer is formed from a hydrocolloid material.

10. An ostomy coupling according to any preceding claim, the ostomy coupling being concave in nature to facilitate use with a flattened or recessed stoma.

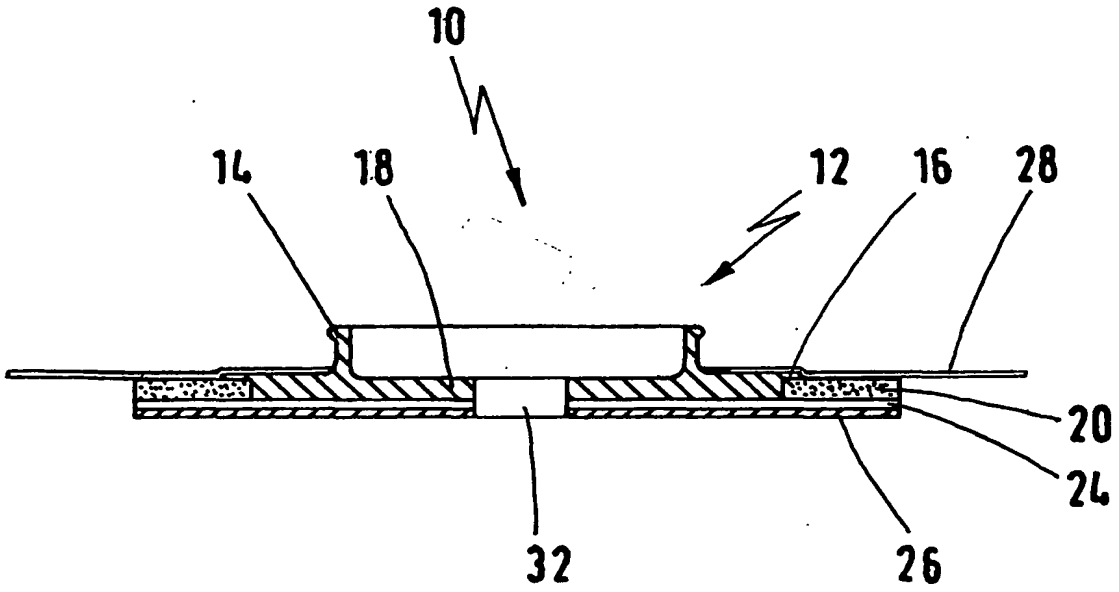

FIG. 1

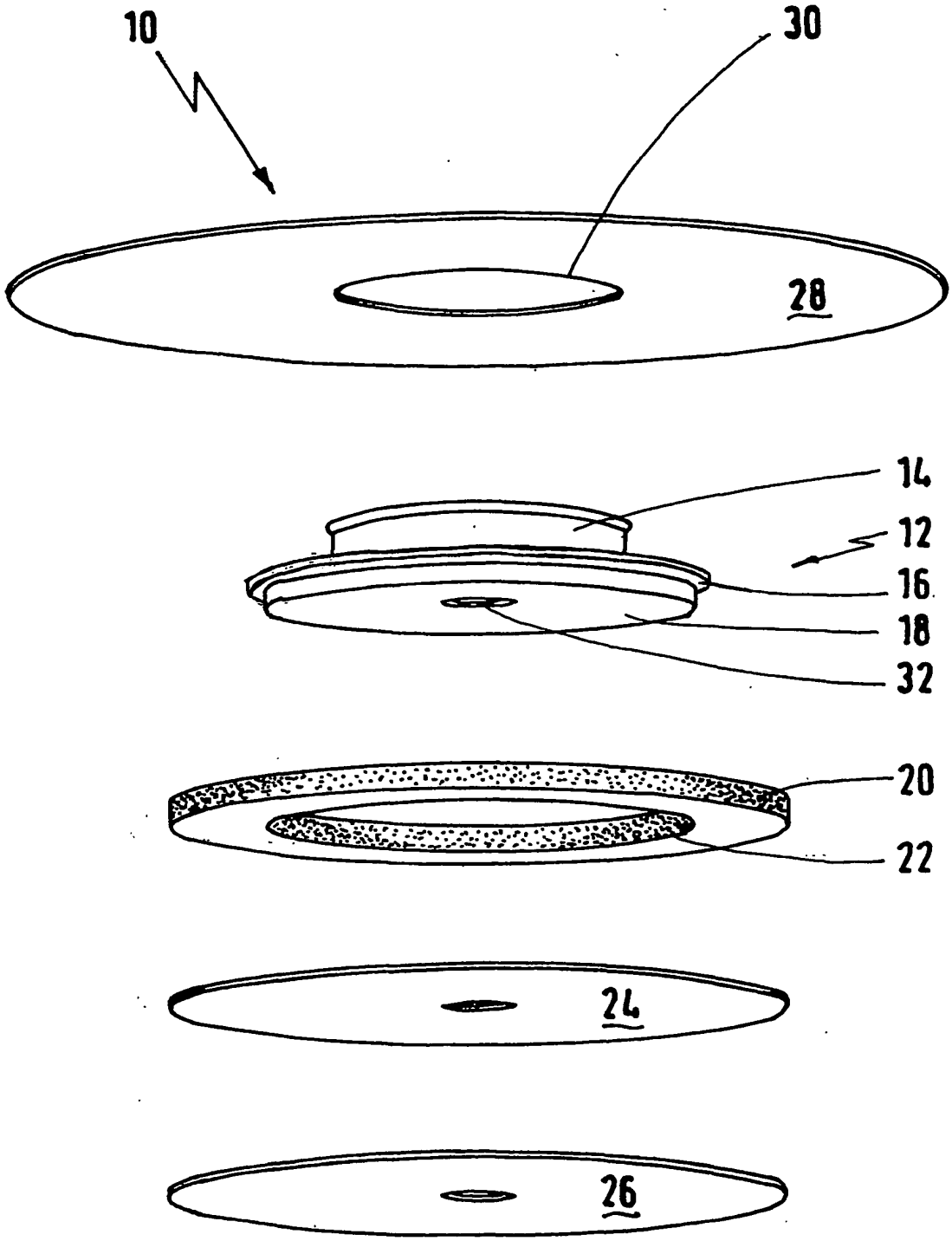

FIG. 2

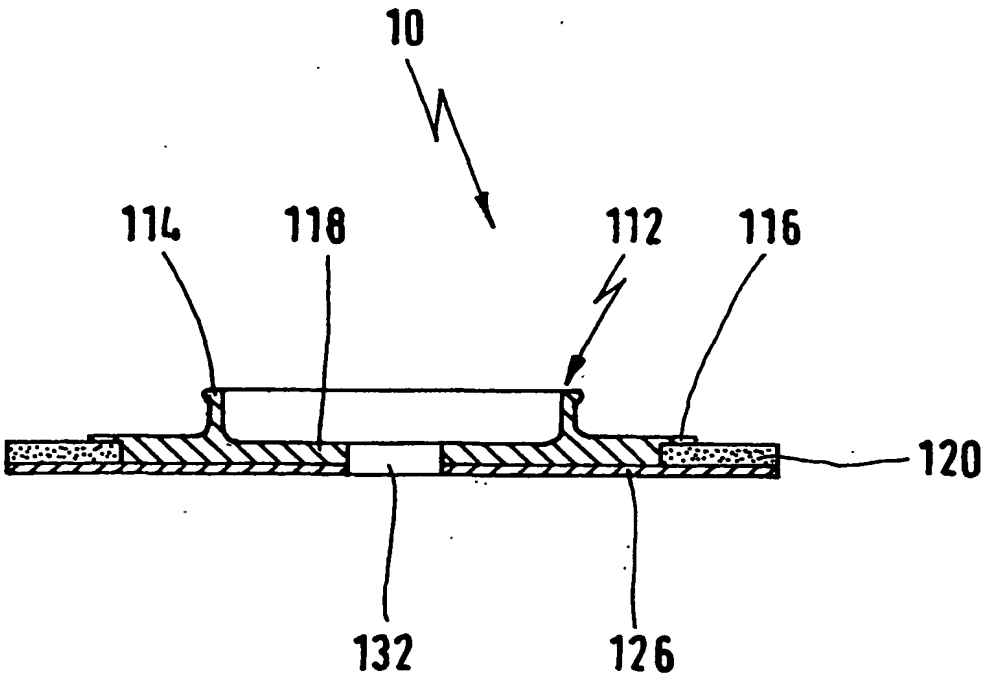

FIG. 3